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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-701,031	11-22-2000	Hannele Tolo	0365-0476P	4589

7590 12-03-2001

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Falls Church, VA 22040-0747

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,031

Applicant(s)

Tolo et al.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Finland on 10 June 1998. It is noted, however, that no copy of the certified copy of the priority document has been received.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Georgiades et al., U.S. patent no. 4732683, 1988, in view of Manabe et al., U.S. patent no. 4808315, 1989. Georgiades et al. teaches inactivation of Sendai virus and other contaminating viruses in interferon alpha preparations by the addition of non-ionic detergents and/or membrane filtration (column 7, lines 1-16, column 12, lines 55-64, and column 14, lines 14-23). Georgiades et al.

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specifically teaches polyoxyethylenesorbitan monolaurate (Tween 20) and monooleate (Tween 80) as well as alkyl polyoxyethylene ethers (such as polyoxyethylene lauryl ether, Brij 35) as claimed in claims 2 and 3. Georgiades et al. further teaches detergent concentrations of 0.01-1.0%, v/v, or 0.1-10 g/l, encompassing the range specified in claim 4. Examples 2 and 3 (column 7, lines 60-68, and column 8, lines 1-29) teach starting amounts of 10,000 IU/ml, within the range specified in claim 6. Interferon alpha subspecies and the advantages of preserving these species during purification are taught in column 1, lines 22-50 and column 3, lines 64-68. Georgiades et al. additionally teaches ultrafiltration and sterile filtration (e.g. column 6, lines 1-20). Gerogiades et al. fails to teach explicitly teach filters for virus removal with a pore size of 10-40 nm. Such filters are taught by Manabe et al. Manabe et al. teaches hollow fiber membranes for the removal of viruses and teaches pore sizes of 0.01-10 μm (column 1, line 46), encompassing the instantly claimed range. It would have been obvious to one of ordinary skill in the art to combine the teachings of Georgiades et al. with those of Manabe et al. to use non-ionic detergents and virus removal filtration to produce interferon alpha preparations as instantly claimed. One of ordinary skill would have been motivated to do so because Georgiades et al. teaches detergent inactivation of virus, and further indicates in column 4, line 5, that membranes can be used with detergents as well. Further, *In re Kerkhoven* (205 USPQ 1069, CCPA 1980) summarizes:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

Both non-ionic detergents and filters are taught by the prior art to be useful for removing viruses; thus, it would be *prima facie* obvious for one of ordinary skill to combine them.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

“Virus-safe” is not defined in the specification; one of skill in the art would not know what level of virus would be considered “safe”. An “efficient amount” is similarly undefined. In claim 1, “the group of interferons” lacks an antecedent basis. Similarly, “the solution” in claim 5 lacks an antecedent basis. “The activity of the α -interferon solution” in claim 6 lacks an antecedent basis. Claims 9 and 10 are indefinite because it is not clear when “prefiltering” and “sterile filtering” occur.

Claim 1 is an improper Markush group. A Markush group recites members as being “selected from the group consisting of A, B and C.” See *Ex parte Markush*, 1925 C.D. 126 (Comm’r Pat. 1925).

Claim 15 is improperly dependent. Claim 1 is drawn to a method, not a composition.

NO CLAIM IS ALLOWED.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

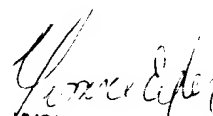
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
November 30, 2001


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
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